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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,905	04/02/2001	Sharat Singh	0225-0033.22	2421

33603 7590 05/17/2004

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EXAMINER	
TUNG, JOYCE	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary	Application No.	Applicant(s)	
	09/824,905	SINGH ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/21/2004 has been entered.

The applicant's Response (filed 1/21/2004) to the Office action has been entered. Claims 11-24 are pending.

1. Applicant's arguments with respect to claims 11-24 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705) in view of Kline et al. (5,459,078).

Grossman et al. disclose a method of detecting a plurality of different sequences in a target sequence involving a plurality of sequence probes (See column 2, lines 54-56). The probe comprises the features of the e-tag probe as claimed in claims 11-23. The probe includes a binding polymer, a polymer chain that imparts to that probe, a distinctive ratio of charge/transnational frictional drag and a reporter attached to the binding polymer (See column 20, lines 52-57). It suggests that the probe has a charge. The binding polymer is an oligonucleotide including at least 10-20 bases allowing hybridization to the target polynucleotide (See column 6, lines 66-67 and column 7, lines 1-10). Other binding polymers are analogs of polynucleotides, such as deoxynucleotides with thiophosphodiester linkage (See column 7, lines 11-19). The polymer chain has a ratio of charge/translational frictional drag, which is evidenced by a distinctive electrophoretic mobility in a non-sieving matrix (See column 7, lines 50-64). The polymer chain can be polyethylene oxide (PEO) or a polypeptide chain where the chains are attached to different-sequence binding polymers (See column 3, lines 11-18). The teachings suggest that the charge/translational frictional drag is consisted of carbon, hydrogen, oxygen, phosphorus, nitrogen, sulfur and boron as recited in claim 12. The label refers to a fluorophore or chromophore (See column 6, lines 39-44). The features of Grossman et al.'s probe suggest the features of the claimed e-tag probe.

Grossman et al do not disclose the kit comprising a capture agent and a plurality of electrophoretic probe in which the oligonucleotide portion is attached with a capture ligand, the capture ligand is biotin and capture agent is avidin or streptavidin.

Kline et al. disclose a competitive digoxin assay method (See the Abstract) and a kit comprising the assay device with its incorporated reagents (See column 29, lines 50-56). A test sample suspected of containing the analyte of interest may be contacted with the capture reagent to form a charged capture reagent/analyte complex. The complex is then contacted to the oppositely charged solid phase to attract, attach and immobilize the capture reagent/analyte complex (See the Abstract). The test sample can be derived from any desired source (See column 8, lines 5-18). The analyte can be any substance for which there exists a naturally occurring specific binding member or for which a specific binding member can be prepared (See column 8, lines 19-32). The specific binding pair can be biotin and avidin, and complementary nucleotide sequences including probe and capture nucleic acid sequence used in DNA hybridization assays to detect a target nucleic acid sequence (See column 7, lines 37-53).

One of ordinary skill in the art would have been motivated to apply the binding pair biotin and avidin to the nucleic acid probe of Grossman to make the electrophoretic probes for detecting the presence of absence of one or more of a plurality nucleic sequence in a sample. Kline et al. disclose that the invention is not limited to immunoreactive assay and any assays using specific binding reactions between the analyte and assay reagents can be performed (See column 7, lines 28-33) and the ion-capture technique increases the potential number of complexes that can be immobilized on a solid support. One of the ordinary skill in the art would have also been motivated to make the kit comprising all elements as taught by Kline et al.

because it was also routine practice in the art for conveniently performing the method. It would have been prima facie obvious to make the kit comprising the capture reagent and a plurality of electrophoretic probes with a capture ligand for detecting the presence or absence of one or more of a plurality nucleic acid sequence in a sample.

4 Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705) in view of Kline et al. (5,459,078), as applied to claims 11-23 above, and further in view of Ullman et al. (6,251,581B1 (2001))

The teachings of Grossman et al. and Kline et al. are set forth in section 3 above.

Grossman et al. and Kline et al. do not disclose the detectable labels, which are the compounds, listed in claim 24.

Ullman et al. disclose a method for determining an analyte in a medium (See the Abstract). The method applies a chemiluminescent compound associated with a specific binding pair member (See column 4, lines 54-65 and column 5, lines 8-14). The compound has the same structure as the compound listed in claims 24 (See column 42-58).

One of ordinary skill in the art at the time of the invention was made would have been motivated to apply the chemiluminescent compound of Ullman et al. to the probe of Grossman et al. in order to construct the set of electrophoretic tag probe of instant invention. Ullman et al. disclose a chemiluminescent compound to bind to a specific binding pair complex so that the detection may be performed without heating the medium to produce light and conducted at a constant temperature (See column 7, lines 28-31). If the analytes are nucleic acid, by avoiding heating, the nucleic acid analytes would not be inactivated and thus the sensitivity of the method is increased. It would have been prima facie obvious to apply the fluorescent molecules to the

electrophoretic release tag to construct the plurality of electrophoretic probe to avoid inactivating nucleic acid analytes. Thus it would have been prima facie obvious to apply the fluorescent molecules to the electrophoretic release tag to construct the plurality of electrophoretic probe.

Summary

5. No claims are allowable.

6. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung J.T
May 7, 2004

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
5/10/04